

### **REMARKS**

Claims 1-9 are pending in the application.

It is noted the current Office Action lists claims 14-15 and 18-20 as withdrawn, but contains a substantive rejection of these claims on page 4, paragraph 5. Claims 10-20 were withdrawn in response to the restriction requirement mailed March 22, 2007. On June 17, 2008, the examiner confirmed to the undersigned claims 10-20 are withdrawn, only claims 1-9 are pending and the rejection of claims 14-15 and 18-20 is moot.

#### **Claim Rejections**

##### **35 U.S.C. § 102**

In the Office Action on page 2, paragraph 2, claims 1-2 and 5 were rejected under 35 U.S.C. § 102(c) as being anticipated by U.S. Patent No. 5,591,139 to Lin et al. ("Lin '139"). The only stated basis for the rejection appears on page 7 of the Office Action, which states:

Applicant's argument that the Lin reference does not show a conductor on a majority of a channel (sic) please note that Lin states paragraph 26 of the detailed description "in addition to resistors, micropumps and microvalves (neither is shown) may be incorporated onto the microneedle. For example, the resistors may also be part of a bubble-powered micropump coupled to an actuator."

Applicants respectfully traverse the rejection. The cited portion of Lin '139 does not disclose or suggest at least one conductor disposed in the microchannel along a majority of the length of the microchannel as in claim 1. There is no disclosure of where the micropumps or microvalves would be "incorporated onto the microneedle", and no disclosure at all of disposing such pumps or valves in the microchannel. As discussed below, the portion of the microchannel that is not in the interface region of Lin '139 is reserved for the detector resistors, and should not have heating resistors. The portion of Lin '139 cited by the examiner merely refers back to the preferred embodiment (FIG. 2A) discussed in col. 8, lines 15-23, which states:

A single resistor is shown in FIGS. 4A and 4B **to illustrate its positioning** [i.e., in the interface region]. However, in a preferred embodiment five resistors 60 form a thermally-driven cascaded

bubble pump (FIG. 2A). In operation, the resistor furthest from the needle tip is heated and produces a single vapor bubble. Then, the adjacent resistor is heated and the bubble is moved sequentially down the line of resistors toward the distal end of the needle shaft. The resistors are heated quickly and sequentially, so that precise fluid control is possible. If a cascaded bubble pump is not employed, a fluid may move down the needle shaft simply by means of gravity.

This portion of Lin '139 stresses that the heating resistors 60, regardless of their number (single or multiple) or form (single heater, or serially arranged for a bubble pump), are located only in the interface region 11 of the microneedle and not anywhere else. This is consistent with the entire thrust of Lin '139, which teaches that there should not be any microheater, let alone the specifically claimed conductor, or any other means to achieve microheating, located in the remaining majority portion of the microflow channel. The remainder of the microflow channel not including the interface region is specifically reserved for detector resistors 62, which are not heating resistors or conductors. See, Lin col. 3, lines 33-43 and 63-66. In contrast, the presently claimed invention includes a conductor that is disposed in and extends along a majority of the microchannel.

In addition, the size of the heating resistors 60 (50  $\mu\text{m}$  long x 2  $\mu\text{m}$  wide - see col. 5, lines 18 and 29) relative to the interface region 11 (1.5 mm - dimension X in FIG. 2A) and the overall length of the microneedle device (2.5-8.5, dimension X plus dimension Y in FIG. 2A) is so small that there is no teaching or suggestion of the heating resistor(s) being present in anything even remotely close to the claimed "majority of the length" of the microchannel.

Since all the heating resistors of Lin '139 must be in the interface region, and all the heating resistors are small, any further micropumps or microvalves referred to in Lin must also be located in the interface region and be small, and regardless of their number, cannot form at least one conductor disposed in the microchannel along a majority of the length of the microchannel as in claim 1. As a result, the Lin '139 reference does not contain each and every limitation of claim 1 and cannot anticipate claim 1. Claims 2 and 5 depend from claim 1 and recite additional features and are likewise allowable. Accordingly, Applicants respectfully request this rejection be withdrawn.

35 U.S.C. § 103 – Claims 6-7 and 9 (Lin ‘139 in view of Ferguson)

In the Office Action on page 3, paragraph 4, claims 6-7 and 9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin in view of U.S. Published Patent Application No. 2003/0209534 to Ferguson (“Ferguson”). Applicants respectfully traverse this rejection.

Applicants assert this rejection (made based upon the identical Lin ‘801), first made in the September 7, 2005 Office Action, and referred to in the previous response, overcome by the amendment in response thereto filed November 18, 2005. For convenience the Applicants reassert the previously stated arguments for patentability of claim 1 as follows:

Claim 1, from which claims 6, 7 and 9 depend, has been recited hereinabove. Applicants submit that neither Lin ‘139 nor Ferguson, alone or in combination, teach or suggest the present invention as claimed. Moreover, Applicants submit there would have been no motivation to combine the references, and even if such combination were made, the claimed invention would not result therefrom.

The Lin ‘139 reference relates to a micromachined needle having an interface region 11 and elongated shaft portion 14 and enclosed microchannel 78 disposed along the length of the interface region 11 and shaft portion 14. The enclosed microchannel 78 includes a microheater 60 only in the interface region 11 and specifically does not include any heating device in the shaft region. See, *e.g.*, FIG 1A. Since the Lin ‘139 reference does not disclose, teach or suggest a microheater comprising at least one microchannel having a length formed on a substrate and further comprising at least one conductor disposed in said microchannel along a majority of the length of said microchannel as in claim 1, the teachings of the Lin ‘139 reference would not motivate one skilled in the art to look to Ferguson to achieve the presently claimed invention. Thus the combination of Lin ‘139 and Ferguson is improper. In any event, the combination does not result in the claimed invention.

The shortcomings of the Lin ‘139 reference have been set forth in detail. Nothing in Ferguson even remotely suggests at least one conductor disposed in a microchannel along a majority of the length of a microchannel as in claim 1. Accordingly, Ferguson does not remedy the deficiency in the Lin ‘139 reference.

The combination of the teachings of Lin ‘139 and Ferguson result in a microheater disposed

only in an interface region of a microneedle having a substrate comprising quartz and borosilicate glass. That combination is not the invention of claim 1, let alone dependent claims 6, 7 and/or 9.

Based on the foregoing, the Applicants submit claims 6, 7 and 9, which depend from claim 1 and recite additional features, are not obvious in view of the cited references. Accordingly, Applicants respectfully request this rejection be withdrawn.

35 U.S.C. § 103 – Claim 3 (Lin ‘139 in view of Kenny)

On page 5 of the Office Action, paragraph 6, claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin ‘139 in view of Kenny (US 6,551,849, “Kenny”). Applicants respectfully traverse this rejection. Claim 3 depends from claim 1 and recites further features, *i.e.*, the conductor comprises an aluminum alloy comprising 99% aluminum and silicon and copper. The shortcomings of Lin ‘139 with respect to claim 1 have been detailed hereinabove. Kenny cannot cure these shortcomings. Moreover, Kenny does not disclose the alloy of claim 3. Since Lin ‘139 does not teach or suggest the invention of claim 1, and Kenny does not disclose the limitations of claim 3, the combination of references cannot result in the invention of claim 3. Applicants request this rejection be withdrawn.

35 U.S.C. § 103 – Claims 4 and 8 (Lin in view of Yamazaki and further in view of Ueno)

On page 6 of the Office Action, paragraph 7, claims 4 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin ‘139 in view of Yamazaki (US 6,165,876, “Yamazaki”) and further in view of Ueno et al (US 2002/00224662, “Ueno”). Applicants respectfully traverse this rejection. Claims 4 and 8 depend from claim 1 and recite additional features. As set forth in detail hereinabove, the Lin ‘139 reference does not disclose the invention of claim 1. The teachings of Yamazaki cannot cure the deficiencies of the Lin ‘139 reference to achieve the invention of claims 4 and 8. The combination of Lin ‘139 and Yamazaki at best result in a microneedle device having an enclosed microchannel with a boron ion-implanted microheater only in the interface region and specifically does not include any heating device in the shaft region. This is not the invention of claims 4 and/or 8. Nor can the additional reference to Ueno cure the deficiencies of Lin ‘139 alone

or in combination with Yamazaki. Accordingly, Applicants respectfully request this rejection be withdrawn.

Applicants submit that all claims pending in the patent application are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for the RCE is included herewith. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

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Respectfully submitted,

/s/Timothy X. Gibson/  
Timothy X. Gibson, Reg. No. 40,618  
GIBSON & DERNIER, LLP  
*Attorney for Applicants*  
900 Route 9 North, Suite 504  
Woodbridge, New Jersey 07095  
(732) 634-7634

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